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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,245

Applicant(s)

DARROW ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7-12, 18-41, 45, 46 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-12, 18-41, 45, 46 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

FINAL ACTION

Applicant's amendment of 6-30-05 has been fully considered.

Claims 2-6, 13-17, 42-44, 47-50 and 52-79 have been cancelled.

Claims 1, 7-12, 18-41, 45, 46 and 51 are pending.

The amended claims 1, 7-12 and applicant's argument have overcome the previous rejection of Statutory Double Patenting, but raise the issue of ODP (new ground of rejection). The original claims 18-22 and 37-41 still claim the same compounds as those in US'743. The amended claims 23-36, 45, 46 and 51 have not overcome the previous ODP rejection. A new ODP rejection is made for the amended claims 1, 2, 7-12, 21 and 22 while the previous ODP is maintained for claims 23-36, 45, 46 and 51.

The preliminary amendment of 5-23-02 had been considered in the previous action.

Double Patenting

The **nonstatutory double patenting** rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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1. Claims 18-20, 24-27, 29-36, 40, 45, 46 and 51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-12, 16-18 21-25, 27-34, 38, 43, 44 and 49 of U.S. Patent No. **6,372,743 B1**. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

- a. The instant claims 18-20 depend on claim 1 but recite K_1 values that are the same as those recited in claims 16-18 of US'743.
- b. The instant claim 24 has also been amended with narrower scope, but still falls within the scope of formula I recited in claim 22 of US'743 because of the following overlapping subject matters:
 - i. R^5 is C_1 - C_6 alkyl, ... substituted with 1-5 groups independently selected at each occurrence from C_1 - C_6 alkyl, C_3 - C_{10} cycloalkyl,..., and
 - ii. The claim includes an unsubstituted (C_3 - C_{10} cycloalkyl), C_1 - C_6 alkyl group in R^5 of US'743.
 - iii. Also in the proviso C_1 - C_6 alkyl is substituted with C_1 - C_6 alkyl to give C_7 - C_{10} alkyl group. This differs from applicants C_1 - C_6 alkyl by a $-CH_2-$ group, homologs are obvious.
- c. The instant claims 25-27 depend (directly or indirectly) on claim 24, and recite the same limitations as those recited in claims 23-25 of US'743.
- d. The instant claims 29-36 indirectly depend on claim 24, and recite the same limitations as those recited in claims 27-34 of US'743.

e. The instant claim 40 recites many species that are the same as those recited in claim 38 of US'743.

f. The instant claims 45, 46 and 51 depend on claim 24, and recite the same limitations as those recited in claims 43, 44 and 49.

Because compounds, compositions and method of treatment claimed herein only differ in scope with those claimed in US'743, it would have been within the level of one skilled in the art to recognize that the subject matter claimed herein is a subgenus of those claimed in US'743. Thus, at the time that the invention was made, it would have been obvious to select the instantly claimed formula I in view of that claimed in US'743.

2. Claims 1, 7-12, 18-41, 45, 46 and 51 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-19, 22, 23 and 25-31 of U.S. Patent No. **6,476,038 B1**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the amended claims still have a scope that falls within the scope of those in US'038.

Although variables R⁵ and R⁶ in US'038 are not indicated as being substituted, their definition does not exclude substitution either. Therefore, the instant formula I is still obvious over formula I of US'038 as being a subgenus of formula I of US'038.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 lacks antecedent basis because it depends on claim 28, but recites a species having *piperidin-2-ylmethyl*, which would require B and R⁵ to form a ring whereas claim 28 recites B as a -CH₂- group.

References cited on PTO-892

References cited on PTO-892 show state of the art. They either do not teach or suggest a substituent equivalent to the instant R⁵, or do not have an effective filing date prior to the priority date of this application.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

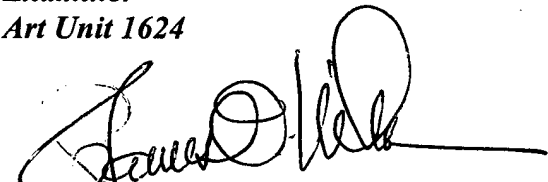
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tamthom N. Truong
Examiner
Art Unit 1624

9-17-05


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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